K083645

SECTION 5. 510(K) SUMMARY

FEB 2 4 2009

Submission Correspondent:	5-Star Medical, Inc. Phone: (504) 952-9729 Email: terry@pvmed.net Contact: Terry L. Ancar
Submission Sponsor:	5-Star Medical, Inc. 11515 Prosperous Dr. Odessa, FL. 33556 Phone: (727) 753-0410 Fax: (727) 376-2868 Email: terry@pvmed.net Contact: Terry L. Ancar
Date summary prepared:	October 30, 2008
Device trade name:	RadStar Digital Imaging System
Device common name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Device classification name:	MQB at 21 CFR Part 892.1650
Legally marketed devices to which the device is substantially equivalent:	K081648 Canon CXDI-60G K024147 Varian PaxScan 4030
Description of the device:	The RadStar Digital Imaging System consists of two components, a solid state x-ray imager and software for viewing the captured images on a Windows-based computer. The device is intended for incorporation into a complete x-ray system by qualified x-ray service personnel. The RadStar Digital Imaging System will display high quality images in less than 5 seconds over a wide range of X-Ray dose settings.

Intended use of the device:	The RadStar DDR Digital Imaging System is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. The device is intended for incorporation into a complete x-ray system by qualified x-ray service personnel. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.
Technological characteristics:	The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology.
Conclusions:	There are no significant differences between the RadStar Digital Imaging System and the predicate devices and therefore, the RadStar Digital Imaging System does not raise any questions regarding safety and effectiveness. The RadStar Digital Imaging System, as designed, is as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

5 Star Medical, Inc.
% Mr. Terry L. Ancar
President
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AUG 23 2013

Re: K083645
Trade/Device Name: RadStar DDR Digital Imaging System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 12, 2009
Received: January 21, 2009

Dear Mr. Ancar:

This letter corrects our substantially equivalent letter of February 24, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K083645

Device Name: RadStar DDR Digital Imaging System

Indications for Use: The RadStar DDR Digital Imaging System is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is intended for incorporation into a complete x-ray system by qualified x-ray service personnel. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

Prescription Use X
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083645